
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, D.C. 20549

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): May 16, 2016

GALECTIN THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-31791
(Commission
File Number)

04-3562325
(IRS Employer
Identification No.)

**4960 PEACHTREE INDUSTRIAL BOULEVARD, Ste 240
NORCROSS, GA 30071**
(Address of principal executive office) (zip code)

Registrant's telephone number, including area code: (678) 620-3186

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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SECTION 7 – REGULATION FD

Item 7.01 Regulation FD Disclosure.

On May 16, 2016, Galectin Therapeutics Inc. (the “Company”) issued the press release attached hereto as Exhibit 99.1.

The information in this report is being furnished pursuant to this Item 7.01 and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933 or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this report.

SECTION 9 – FINANCIAL STATEMENTS AND EXHIBITS

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, Galectin Therapeutics Inc. has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Galectin Therapeutics Inc.

Date: May 16, 2016

By: /s/ Jack W. Callicutt
Jack W. Callicutt
Chief Financial Officer



Galectin Therapeutics Announces Positive Interim Results from Phase 2a Trial with GR-MD-02 in Moderate-to-Severe Plaque Psoriasis

A significant clearing of psoriasis in first four patients prompts the extension of treatment for an additional 12 weeks

Conference call to be held tomorrow at 9:00 a.m. Eastern time

NORCROSS, Ga. (May 16, 2016) –Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, announces positive interim results from an exploratory, open-label, Phase 2a clinical trial with GR-MD-02 in patients with moderate-to-severe plaque psoriasis. All four patients who received 12 weeks of therapy (six doses of GR-MD-02) had significant improvement in their plaque psoriasis. Given the improvement noted, Galectin has extended the treatment duration to 24 weeks.

This Phase 2a open-label trial is being conducted in 10 patients with moderate-to-severe plaque psoriasis who have $\geq 10\%$ of their skin surface area affected and a PASI (Psoriasis Area and Severity Index) of ≥ 12 points. The enrolled patients are being treated with 8 mg/kg of GR-MD-02 every other week for a total of seven infusions, with the seventh infusion being administered on the same day the 12-week PASI is scored. The primary efficacy assessment in this study is improvement in PASI, as described in detail in a recent [CEO Perspective](#).

“Each of the four patients who received six doses of GR-MD-02 over 12 weeks of therapy reported improvement in their symptoms related to psoriasis,” said Simon A. Richie, M.D., Staff Dermatologist, Chief of Phototherapy and Tele-Dermatology at San Antonio Military Health System and Principal Investigator of the trial. “Moreover, all four patients had significant improvement in PASI measurements. It is uncommon for patients with moderate-to-severe plaque psoriasis to spontaneously improve without treatment. The drug infusions were well tolerated by patients, and the two adverse events that were noted, one infiltration of the intravenous catheter and one headache during infusion, were mild and transient.”

Interim results are shown in the table below.

Patient	Baseline PASI Score	After 3 Doses		After 6 Doses	
		PASI Score	Percent improvement from baseline	PASI Score*	Percent improvement from baseline
1	13.6	9.2	32%	8.1	40%
2	14.6	12.5	14%	7.9	46%
3	12.3	9.1	26%	10.6**	14%
4	12.8	7.2	44%	4.3	66%

* PASI performed on same day as 7th infusion

** PASI performed 1 week following 7th infusion; patient taken off systemic therapy for psoriasis one month prior to starting therapy

“These interim results on four patients in this exploratory clinical trial demonstrate a potentially important clinical effect of GR-MD-02 in clearing moderate-to-severe plaque psoriasis,” said Peter G. Traber, M.D., Galectin’s president, chief executive officer and chief medical officer. “While these patients were not evaluated for fatty liver disease, these findings may have implications for activity in our main therapeutic program targeting NASH, a disease where there is a high incidence of psoriasis and increased galectin-3 in the skin. We are excited to extend this trial to better determine the full potential of GR-MD-02 as a treatment for moderate-to-severe psoriasis.”

The link, if any, between non-alcoholic steatohepatitis (NASH) and psoriasis is not completely understood. However, patients with psoriasis have more than a two-fold higher incidence of NASH, the severity of which tends to correlate with the severity of liver fibrosis and galectin-3 is increased in psoriatic skin. The genesis of this Phase 2a psoriasis treatment study was a 17 month remission in a NASH patient with severe psoriasis who participated in the Company’s Phase 1 study cohort of 4 mg/kg of GR-MD-02 for the treatment of NASH ([see CEO Perspective](#)).

“This Phase 2a clinical trial will be extended so that all patients, including the four who have already completed treatment, will receive a total of 13 drug infusions,” added Dr. Richie. “The one patient among the initial four with the least objective response in PASI was on a systemic retinoid therapy (acitretin) which was stopped one month before entering this study. Stopping this drug can lead to a long-term rebound effect, which may have contributed to the lower treatment response. Doubling the duration of therapy, and continued enrollment to the full 10 patients, will help us to evaluate the full therapeutic potential of GR-MD-02 in psoriasis.”

The announced results are interim in that the originally scheduled 12 weeks of data has been obtained from only four of the ten patients who will participate in the trial. It is further interim in that the positive information obtained to this point has led to the trial being extended for all 10 study subjects in the trial.

Conference Call and Webcast

Galectin Therapeutics management will host a conference call at 9:00 a.m. Eastern time tomorrow to discuss this press release.

To access the conference call, U.S.-based listeners should dial 866-634-2258 and international listeners should dial 330-863-3454. All listeners should provide the following passcode: 10667177. Individuals interested in listening to the live conference call via the Internet may do so by logging on to the Company’s website at www.galectintherapeutics.com.

Following the conclusion of the conference call, a replay will be available through May 23, 2016 and can be accessed by dialing (855) 859-2056 from within the U.S. or (404) 537-3406 from outside the U.S. All listeners should provide passcode 10667177. The webcast will be available on the Company’s website at www.galectintherapeutics.com for 90 days.

About Psoriasis

Psoriasis, which manifests most often as plaque psoriasis, is a chronic, relapsing, inflammatory skin disorder. Although plaque psoriasis is rarely life threatening, it often is intractable to treatment. According to the International Federation of Psoriasis Associations, about 3% of the

world's population has some form of psoriasis. In the U.S. there are about 150,000 new cases every year, and psoriasis affects about 2% of the U. S. population, according to the Cleveland Clinic.

About GR-MD-02

GR-MD-02 is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of fatty liver disease and fibrosis. Galectin-3 plays a major role in diseases that involve scarring of organs including fibrotic disorders of the liver, lung, kidney, heart and vascular system. The drug binds to galectin proteins and disrupts their function. Preclinical data in animals have shown that GR-MD-02 has robust treatment effects in reversing liver fibrosis and cirrhosis.

About Galectin Therapeutics

Galectin Therapeutics is developing promising carbohydrate-based therapies for the treatment of fibrotic liver disease and cancer based on the Company's unique understanding of galectin proteins, which are key mediators of biologic function. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. The Company is pursuing a development pathway to clinical enhancement and commercialization for its lead compounds in liver fibrosis and cancer. Additional information is available at www.galectintherapeutics.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or future financial performance, and use words such as "may," "estimate," "could," "expect" and others. They are based on management's current expectations and are subject to factors and uncertainties that could cause actual results to differ materially from those described in the statements. These statements include those regarding the hope that Galectin's development program for GR-MD-02 will lead to the first therapy for the treatment of fatty liver disease with cirrhosis and/or an additional therapy for the treatment of moderate to severe psoriasis and that positive results in treating psoriasis may have implications for the treatment of NASH. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that interim results in only four patients may not be indicative of the results when all 10 patients are treated in the Phase 2a trial, and even if the Phase 2a open label trial when completed reports positive results, those results may not be repeated in larger blinded trials that are required for licensing. Further, Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of GR-MD-02 or any of its other drugs in development. The Company's current clinical trial, when completed, and any future clinical studies may not produce positive results in a timely fashion, if at all, and could prove time consuming and costly. Plans regarding development, approval and marketing of any of Galectin's drugs are subject to change at any time based on the changing needs of the Company as determined by management and regulatory agencies. Plans regarding development, approval and marketing of any of Galectin's drugs are subject to change at any time based on the changing needs of the Company as determined by management and regulatory agencies. Regardless of the results of any of its development programs, Galectin may be unsuccessful in developing partnerships with other companies or raising additional capital that would allow it to further develop and/or fund any studies or trials. Galectin has incurred operating losses since inception, and its ability to successfully develop and market drugs may be

impacted by its ability to manage costs and finance continuing operations. For a discussion of additional factors impacting Galectin's business, see the Company's Annual Report on Form 10-K for the year ended December 31, 2015, and subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause its views to change, management disclaims any obligation to update forward-looking statements.

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